PTO/SB/21 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM		Application Number	10/763,431	
		Filing Date	January 22, 2004	
		First Named Inventor	Lutz BIEDERMANN	
		Art Unit	3733	
(to be used for all correspondence after initial filing)		Examiner Name	P. Philogene	
Total Number of Pages in This Submission 15		Attorney Docket Number	564682000100	
ENCLOSURES (Check all that apply)				
X Fee Transmittal Form	X Drawing(s)		After Allowance Communication to TC	
Fee Attached	Licensing-related Papers		Appeal Communication to Board of Appeals and Interferences	
Amendment/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)	
After Final	Petition to Convert to a Provisional Application		Proprietary Information	
Affidavits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Address		Status Letter	
Extension of Time Request	Terminal Disclaimer		X Other Enclosure(s) (please Identify below):	
Express Abandonment Request	Request for Refund		Request for Republication Under 37 CFR 1.221(a); (2	
Information Disclosure Statement	CD, Number of CD(s)		pages)  Application U.S. Serial No.	
Certified Copy of Priority Document(s)	Landscape Table on CD		10/763,431 (11 pages)	
Reply to Missing Parts/ Incomplete Application	Remarks			
Reply to Missing Parts under 37 CFR 1.52 or 1.53				
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT				
MORRISON & FOERSTER LLP				
Signature				
Printed name Barry E. Bretschnei	Barry E. Bretschneider			

Reg. No.

28,055

Date

September 23, 2010

Docket No.: 564682000100

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Lutz BIEDERMANN et al.

Application No.: 10/763,431

Confirmation No. 6801

Filed: January 22, 2004

Art Unit: 3733

For: BONE SCREW

Examiner: Pedro Philogene

# **REQUEST FOR REPUBLICATION UNDER 37 CFR 1.221(a)**

Mail Stop PGPUB Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants respectfully request republication of this application.

This Request for Republication pursuant to 37 CFR 1.221(a) is accompanied by the required publication fee set forth in 37 CFR 1.18(d), the processing fee set forth in 37 CFR 1.17(i), and the application to be republished.

Remarks begin on page 2 of this paper.

Application No.: 10/763,431 Docket No.: 564682000100

Request for Republication Pursuant to 37 CFR 1.221(a)

## **REMARKS**

This application is currently pending and was published on August 5, 2004. Applicants wish to republish the application with the claims as amended in the Supplemental Amendment filed on May 16, 2007. Applicants attach the patent application and the amended claims to be republished in compliance with EFS requirements and MPEP 1730 as set forth under 37 CFR 1.221(a).

If a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No.** 564682000100.

Dated: September 23, 2010

Respectfully submitted,

Barry E. Bretschneider

Registration No.: 28,055

MORRISON & FOERSTER LLP 1650 Tysons Blvd., Suite 400

McLean, Virginia 22102 Telephone: (703) 760-7743

Facsimile: (703) 760-7777

#### BONE SCREW

#### REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of Serial No. 10/037,698, filed November 9, 2001, now U.S. Patent No. 6,736,820, the disclosure of which is incorporated herein by reference.

5

10

15

20

25

# FIELD AND BACKGROUND OF THE INVENTION

[0002] The invention relates to a bone screw having a threaded section and a head and a receiving part at the head end for receiving a rod to be connected to the bone screw, the receiving part possessing an open first bore and a substantially U-shaped cross-section having two free legs provided with a thread and a second bore at the end opposite to the first bore, whose diameter is greater than that of the threaded section and smaller than that of the head and which forms the seat for the head, and a nut or screw working together with the thread.

[0003] Such a bone screw is disclosed, for example, in U.S. Patent No. 5,672,176. In the known bone screw the head is of spherical segment-shaped construction. The bottom of the first bore adjacent to the second bore is likewise of spherical segment-shaped construction so that the spherical head lies on this spherical section. The plane going through the bounding edge is oriented at right angles to the axis of the first bore and the mid-point of the second bore coincides with the axis of the first bore. By this means it is achieved that the threaded section possessing the head is pivotable in a predetermined angle of generally up to 25° about the axis of the first bore so that even after screwing the threaded section into a vertebral segment orientation of the receiving part receiving a rod is possible. At the same time, the size of the pivot angle is limited to the extent that the second bore as a function of the diameter of the head must not exceed d certain size so that the head still has an adequate hold in the receiving part.

[0004] The use of such bone screws is something of a problem in the region of cervical vertebrae. In this case, due to the small dimensions of the cervical vertebrae, it is va-312643

necessary that the screws must always be pivoted to one side and upwards, a greater degree of pivoting being necessary than is the case in the larger thoracic vertebrae and lumbar vertebrae.

### **SUMMARY OF THE INVENTION**

[0005] The aim of the invention is to provide a bone screw which permits a larger pivot angle. This task is solved by a bone screw having a screw member that possess a threaded section, a head and a receiving part at the head end for receiving a rod to be connected to the bone screw. The receiving part has an open first bore and a substantially U-shaped cross-section having two free legs provided with threads, a second bore at the end opposite the first bore having a diameter greater than the diameter of the threaded section and smaller than the diameter of the head, and a seat for the head and a nut or screw acting together with the thread. When viewed relative to the axis of the first bore, the edge bounding the free end of the second bore is asymmetrical.

[0006] Refinements of the invention are identified in the more detailed embodiments described below.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Further features and practical advantages of the invention emerge from the description of exemplified embodiments with reference to the figures.

[0008] Fig. 1 depicts a side elevation of a first embodiment of the invention, partly in sectional representation.

[0009] Fig. 2 shows an enlarged detail of Fig. 1.

[0010] Fig. 3 depicts a side elevation, partly in sectional representation, of a second embodiment of the invention.

[0011] Fig. 4 depicts a corresponding representation of a further embodiment of the invention.

5

10

15

#### DETAILED DESCRIPTION OF THE INVENTION

[0012] The bone screw includes a screw member proper 1 having a threaded section 2 and a head 3. The head is formed in the shape of a segment of a sphere in the region adjoining the threaded section. Coaxial with the thread axis and on the end opposite to the threaded section 2 the head possesses a recess 4 for engagement with a socket screw key.

[0013] The bone screw further comprises a cylindrically constructed receiving part 5. At one end this has a first bore 6 of axially symmetrical construction. On the opposite end a second bore 7 is provided whose diameter is greater than that of the threaded section 2 and smaller than that of the head 3. On the end opposite to the second bore the first bore is open and its diameter is of such a size that that the screw member 1 can be guided through the open end by its threaded section 2 going through this bore and by the head going as far as the bottom of the first bore. The bottom of the first bore is constructed as a spherically shaped region towards the open end, the radius being substantially equal to the radius of the spherical segment-shaped section of the head 3. Furthermore, the receiving part 5 has a U-shaped recess 8 arranged symmetrically relative to the center of the part whose bottom is directed towards the second bore 7 and whose two side legs 13, 14 extend to the open end directed towards the first bore 6. At the free end of the legs 13, 14 a thread for engagement with a screw member constructed as a nut or screw is provided. The nut or screw serves to fix a rod to be inserted into the U-shaped recess 8, it being possible for the nut or screw to act on the rod directly or via a pressure member.

[0014] In the embodiment shown in Figs. 1 and 2, in the direction of the arrow 9, whose direction lies in a plane going through the axis of symmetry of the first bore and which is inclined to the axis of symmetry by a predetermined angle, a circular countersink 10 is made in the edge between the opening plane 11 of the second bore and the edge 12-of the first bore.

5

10

15

[0015] In this manner, as can be seen in the figures, it is achieved that the angle between the axis of the screw member 1 and the axis of symmetry of the first bore is substantially enlarged by comparison with the angle otherwise attainable. At the same time the seat of the screw member 1 in the receiving part is retained.

[0016] In the second embodiment shown in Fig. 3 the interior of the receiving part 5 is constructed as in the first embodiment. The opening plane 11, which bounds the second bore 7, in this embodiment is inclined at a predetermined angle  $\alpha$  to the plane bounded by the second bore 7 so that the normal to this plane 11 and the axis of symmetry of the first bore 15 enclose the angle of inclination. In the case shown this angle  $\alpha$  is 15° as an exemplified embodiment. In this version it is also achieved that the screw member 1 is pivotable in the direction shown by an angle to the axis of symmetry of the-first-bore which is substantially greater than the angle which is achievable in the usual mode of construction.

[0017] Both in the embodiment shown in Fig. 1 and the embodiment shown in Fig. 3 the countersink or chamfer is selected in such a way that in each case a small peripheral section still remains which still belongs to the spherical seat.

[0018] In a fourth embodiment which is not shown the mid-point of the second bore is constructed offset to the side to a small extent, for example by 0.5 mm, relative to the axis of symmetry of the first bore. This lateral offsetting in turn produces the result that the head is held in the mounting formed by the spherically constructed bottom but a greater pivot width is achieved in a side direction.

[0019] In the exemplified embodiments described above four different approaches to a solution are presented. It is also possible to combine the individual approaches with one another; that is, for example, to combine the solution according to the first and second exemplified embodiments or one of the two with the third and/or fourth exemplified

5

10

15

embodiment, or even all four exemplified embodiments in order to achieve, in this way, a still greater possibility for pivoting in at least one direction.

[0020] In the exemplified embodiments described above the spherical bottom of the first bore 6 is constructed in each case as an integral component of the receiving part 5. In a modified embodiment, however, the spherical bottom can also be provided either in a mounting part introduced through the first bore 6 or in a mounting part introduced through the second bore 7. The invention is then used in a corresponding manner to the end that the receiving part together with the insert piece is regarded as one member and the measures described above are taken on this piece assembled in this way.

[0021] The members forming the bone screw are preferably made of titanium.

[0022] In the embodiment shown in Fig. 4 the edge bounding the free end of the second bore viewed relative to the axis of the first bore is of symmetrical construction. The asymmetry is achieved in that the screw 1 has a recess or countersink 16 on its neck engaging on the sphere or the spherical segment so that in the manner shown in Fig. 4 as in the exemplified embodiments previously described the enlarged pivot angle can be achieved.

5

10

#### What Is Claimed Is:

5

10

15

20

25

- 1-5. (Canceled)
- 6. A bone fixation assembly comprising:

a coupling element having an inner surface defining a first bore coaxial with a first longitudinal axis and a second bore, coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect and are in communication with one another;

said coupling element including a seat adjacent a lower end of said coupling element, said seat being defined by the inner surface of said coupling element; and

an anchoring element assembled with said coupling element, said anchoring element having a first end for insertion into bone and a head spaced from the first end, said head being in contact with said seat of said coupling element.

- 7. The assembly of Claim 6 wherein said coupling element has an upper end and a lower end, said first bore extending from said upper end toward said lower end and said second bore extending from said lower end toward said upper end.
- 8. The assembly of Claim 7, wherein said first and second bores are in communication with one another between said upper and lower ends of said coupling element.
- 9. The assembly of Claim 7, wherein said upper end of said coupling element defines a first plane and said lower end of said coupling element defines a second plane, and wherein said first and second planes intersect one another.
- 10. The assembly of Claim 7, wherein said anchoring element projects from said lower end of said coupling element.
  - 11. (Canceled)
- 12. The assembly of Claim 7, wherein said second bore includes a seat adjacent said lower end of said coupling element, and wherein said seat is adapted to engage said anchoring element.

13. The assembly of Claim 12, wherein said anchoring element has a head having a substantially spherical underside adapted to engage said seat.

# 14-16. (Canceled)

5

10

15

20

- 17. The assembly of Claim 13, further comprising a locking element engageable with said coupling element for locking the position of said coupling element with respect to said anchoring element.
  - 18. The assembly of Claim 17, wherein said locking element urges a stabilizing rod toward said lower end of said coupling element which in turn forces said head of said anchoring element against said seat for locking said coupling element and said anchoring element from further movement relative to one another.

## 19. (Canceled)

- 20. The assembly of Claim 6, wherein said coupling element has an exterior surface, an upper end and a lower end, said rod-receiving openings extending from said upper end toward said lower end, and wherein said coupling element comprises cuts between said exterior surface and said rod-receiving openings for minimizing the width of said coupling element.
- 21. The assembly as claimed in Claim 6, wherein said anchoring element is a screw fastener having screw threads extending from said first end toward a second end thereof.
  - 22. A bone fixation assembly comprising:

a coupling element having an upper end defining a first plane, a lower end defining a second plane, and at least one bore extending from said upper end toward said lower end, wherein said first and second planes intersect one another;

an anchoring element assembled with said coupling element, said anchoring element being adapted for insertion into bone; and said coupling having a U-shaped opening that extends from the upper end of said coupling element toward the lower end of said coupling element, wherein the U-shaped element is adapted to receive a stabilizing rod.

- 23. The assembly of Claim 22, wherein said coupling element includes at least one
   bore extending between said upper end and said lower end for receiving said anchoring element.
  - 24. The assembly of Claim 22, wherein said coupling element has a seat shaped to allow said coupling element to pivot with respect to said anchoring element.
    - 25. (Canceled)
- 10 26. The assembly of Claim 24, wherein said head has at least one depression adapted to receive a driver for driving said anchoring element into bone.
  - 27. The assembly of Claim 24, wherein said anchoring element includes a reduced diameter neck for facilitating pivotal movement of said coupling element with respect to said anchoring element.
    - 28. A coupling element having an upper end and a lower end comprising:
  - a first section extending from said upper end toward said lower end of said coupling element, said first section including a first bore coaxial with a first longitudinal axis;
  - a second section extending from said lower end toward said upper end of said coupling element, said second section having a second bore coaxial with a second longitudinal axis that intersects said first longitudinal axis;
  - a U-shaped rod-receiving opening extending from said upper end toward said lower end of said coupling element and being adapted to receive an orthopedic stabilizing rod;

said coupling element having an inner surface defining said first and second bores and a seat adjacent said second bore at said lower end of said coupling element; and

15

an anchoring element having a first end for insertion into bone and a head spaced from said first end, said head being in contact with said seat of said coupling element.

- 29. The coupling element of Claim 28, wherein said second bore includes a seat adjacent said lower end of said coupling element.
- 30. The coupling element of Claim 29, wherein said seat is adapted to engage a head of an anchoring element secured with said coupling element so that said coupling element and said anchoring element are pivotable relative to one another.
  - 31. The coupling element of Claim 30, wherein said seat is adapted to engage an underside of said head of said anchoring element.
  - 32. The coupling element of Claim 28, wherein said coupling element has an outer surface with notches for engagement by an instrument for positioning said coupling element with respect to an orthopedic rod.
    - 33. A coupling element for a bone fixation assembly comprising: an upper end defining a first plane;
    - a lower end defining a second plane;

at least one bore extending between said upper end and said lower end, said at least one bore being adapted to receive an anchoring element, wherein said first plane and said second plane intersect one another;

said coupling element having a U-shaped opening that extends from the upper end of said coupling element toward the lower end of said coupling element, wherein said U-shaped opening is adapted to receive a stabilizing rod.

34. The coupling element as claimed in Claim 33, wherein said coupling element has a first bore extending from said upper end toward said lower end and a second bore extending from said lower end toward said upper end, and wherein said first and second bores are angled relative to one another.

10

15

20

35. A coupling element for a pedicle screw assembly, comprising:

said coupling including an inner surface having a first section at an upper end of said coupling element, said first section defining a first bore extending through said coupling element that is coaxial with a first longitudinal axis;

the inner surface having a second section at a lower end of said coupling element, said second section defining a second bore extending through said coupling element that is coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect one another.

## 36-39. (Canceled)

5

10

15

20

- 40. The assembly of Claim 13, wherein said anchoring element includes a neck adjacent said head having a diameter less than the diameter of said threaded portion for facilitating pivotal movement of said coupling element and said anchoring element relative to one another.
- 41. The coupling element of Claim 30, wherein said inner surface includes threads adjacent said upper end thereof for engaging a locking element for securing an orthopedic rod within said rod receiving openings of said coupling element.
- 42. The coupling element of Claim 34, wherein said locking element has external threads adapted for threading into said internal threads of said coupling element.

# 43-60. (Canceled)

- 61. The assembly of claim 6, wherein said anchoring element is a separate member assembled with said coupling element so that said coupling element and said anchoring element are movable relative to one another.
  - 62. The assembly of claim 6, further comprising a locking element engageable with said coupling element for securing a stabilizing rod within said coupling element.

# ABSTRACT OF THE DISCLOSURE

A bone screw having a screw member possessing a threaded section and a head and a receiving part at the head end for receiving a rod to be connected to the bone screw is provided. The receiving part has on open first bore and a substantially U-shaped cross-section having two free legs provided with a thread. Furthermore, the receiving part has a second bore on the end opposite to the first bore whose diameter is greater than that of the threaded section and smaller than that of the head. On the bottom of the first bore a seat for the head is provided. In order that the screw member can be pivoted to at least one side by an enlarged angle, the edge bounding the free end of the second bore viewed relative to the axis of the first bore is of asymmetric construction.

5

App No.: 10/763,431 Docket No.: 564682000100 Inventor: Lutz BIEDERMANN Title: BONE SCREW

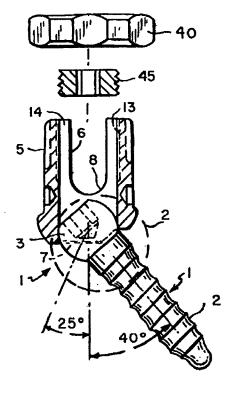


FIG.I

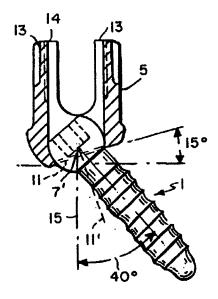


FIG. 3

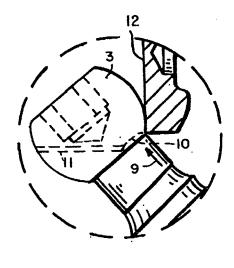


FIG. 2

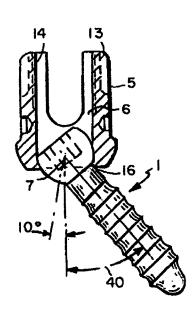


FIG. 4